K073502
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3. 510(k) Summary or 510(k) Statement

MAR 24 2008

SUBMITTER:
VERTEBRON Inc.
80 Hathaway Drive
Stratford, CT 06615
(203) 380-9340

CONTACT PERSON:
Luis Nesprido
Senior Manager Regulatory Affairs

DATE PREPARED:
September 10, 2007

CLASSIFICATION NAME:
21 CFR §888.3080 Intervertebral Body Fusion Device

COMMON NAME:
Intervertebral Body Fusion Device

PROPRIETARY NAME:
VERTEBRON Interbody Fusion System

PREDICATE DEVICES:
Lanx K073144
Globus Medical K072970
Innovative Spine K072120
Abbott Spine K073202

DEVICE DESCRIPTION:
The VERTEBRON Interbody Fusion System consists of various heights, angles and configurations (i.e., square, rectangular D-shaped, etc.). The device is use singly or in pairs to better approximate the anatomical variations observed in different vertebral levels and/or patient anatomy.

The VERTEBRON Interbody Fusion System is comprised of a variety of components fabricated and manufactured from Polyetheretherketone (PEEK) as described by ASTM 2026. This material is utilized due to its radiolucent properties, which aid the surgeon in determining if fusion in the operative site has occurred.

The VERTEBRON Interbody Fusion System has a hollow chamber to permit packing with autogenous bone graft to facilitate fusion, but is of sufficient strength to provide column support even in the absence of fusion for prolonged periods. The superior and inferior surfaces of the construct have a pattern of teeth to provide increased stability and to help prevent movement of the device. Tantalum wire markers (ASTM F560) are inserted into the components to give surgeons a visual aid in determining the location of the implant, both inter and post-operatively.

INTENDED USE:

The VERTEBRON Interbody Fusion System is indicated for use with autogenous bone graft in skeletally mature patients with degenerative disc disease ("DDD") at one or two contiguous spinal levels from L2-S1. DDD is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. These patients should have had six months of non-operative treatment. These DDD patients may have had a previous non-fusion spinal surgery at the involved spinal level(s), and may have up to Grade 1 spondylolisthesis or retrolisthesis at the involved level(s).

The VERTEBRON Interbody Fusion System is implanted via an anterior or posterior approach and is to be combined with cleared supplemental fixation systems include, such as the VERTEBRON PSS Pedicle Screw System.

MATERIALS:

The material used is PEEK ASTM F2026-07e1 Standard Specification for Polyetheretherketone (PEEK) Polymers for Surgical Implant Applications or titanium alloy (TI-6Al-4V) that conforms to ASTM F136 Standard Specification for Wrought Titanium-6 Aluminum-4 Vanadium ELI (Extra Low Interstitial) Alloy for Surgical Implant Applications (UNS R56401) and ASTM F560 Standard Specification for Unalloyed Tantalum for Surgical Implant Applications.

SUBSTANTIAL EQUIVALENCE:

Performance evaluation was conducted in accordance with ASTM F2077-03 – Test Methods for Interbody Fusion Devices and ASTM F2267 – Standard Test Methods for Measuring Load Induced Subsidence of an Interbody Fusion Device Under Static Axial Compression

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Vertebron, Incorporated
% Mr. Luis Nesprido
Senior Manager, Regulatory Affairs
80 Hathaway Drive
Stratford, CT 06615

MAR 24 2008

Re: K073502
Trade/Device Name: Vertebron Interbody Fusion System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: MAX
Dated: February 15, 2008
Received: February 21, 2008

Dear Mr. Nesprido:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041 or (240) 276-3150 or the Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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2. Indications for Use Statement

510(k) Number (if known):

Device Name: VERTEBRON Interbody Fusion System

Indications For Use:

The VERTEBRON Interbody Fusion System is indicated for use with autogenous bone graft in skeletally mature patients with degenerative disc disease ("DDD") at one or two contiguous spinal levels from L2-S1. DDD is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. These patients should have had six months of non-operative treatment. These DDD patients may have had a previous non-fusion spinal surgery at the involved spinal level(s), and may have up to Grade 1 spondylolisthesis or retrolisthesis at the involved level(s).

The VERTEBRON Interbody Fusion System is implanted via an anterior or posterior approach and is to be combined with cleared supplemental fixation systems, such as the VERTEBRON PSS Pedicle Screw System.

Prescription Use: ___X_____ AND / OR Over-The-Counter Use: _____
(Per 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(Please do not write below this line - continue on another page if needed)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for **(Division Sign-Off)**
Division of General, Restorative, and Neurological Devices

510(k) Number K073502